

Effects of tetrodotoxin on cue-induced drug craving in abstinent heroin addicts

Submission date 18/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/06/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
123456

Study information

Scientific Title
Effects of tetrodotoxin on cue-induced drug craving in abstinent heroin addicts

Study objectives

The purpose of this double-blind placebo-controlled study was to assess the effect of a single intramuscular dose of tetrodotoxin (TTX) on cue-induced craving and anxiety in abstinent heroin addicts.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Human Investigation Committee of the Peking University Health Centre on the 27th June 2007 (ref: 21).

Study design

Double blind placebo-controlled, between-subjects design

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Addiction

Interventions

The abstinent heroin addicts were randomly assigned to three treatment groups:

1. Placebo
2. 5 µg tetrodotoxin
3. 10 µg tetrodotoxin

Each treatment was administered once only, intramuscularly, before exposure to a neutral video or a heroin-related video. Craving, anxiety, blood pressure, and heart rate were measured pre- and post-exposure.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Tetrodotoxin

Primary outcome(s)

Cue-induced craving and anxiety.

Both the primary and secondary outcomes were measured at 0 minutes (baseline, before TTX administration), 60 minutes (1 hour after TTX administration), 65 minutes (immediately after the first video presentation), 75 minutes (before the second video presentation), and 80 minutes (immediately after the second video presentation).

Key secondary outcome(s)

Heart rate and blood pressure.

Both the primary and secondary outcomes were measured at 0 minutes (baseline, before TTX administration), 60 minutes (1 hour after TTX administration), 65 minutes (immediately after the first video presentation), 75 minutes (before the second video presentation), and 80 minutes (immediately after the second video presentation).

Completion date

20/03/2008

Eligibility**Key inclusion criteria**

1. Men or non-pregnant/nursing women 18 - 45 years old
2. Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM- IV) criteria for heroin dependence, but opiate-free for at least one month
3. No use of cocaine and other drugs

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

45

Key exclusion criteria

1. Current or past cardiovascular disease
2. History of allergy (food, medicine)
3. Current or past psychiatric illness
4. Neurological signs and/or history of neurological disease
5. Current medical illness
6. Participation in other clinical trials of medications within the past three month

Date of first enrolment

08/02/2008

Date of final enrolment

20/03/2008

Locations

Countries of recruitment

China

Study participating centre

National Institute on Drug Dependence

Beijing

China

100083

Sponsor information

Organisation

The National Basic Research Program of China (973 Program) (China)

ROR

<https://ror.org/027s68j25>

Funder(s)

Funder type

Government

Funder Name

The National Basic Research Program of China (973 Program) (China) (ref: 2007CB512302)

Funder Name

The National High Technology Research and Development Program of China (863 Program) (China) (ref: 2006AA02Z4D1)

Funder Name

The China-Canada Joint Health Research Program (China) (ref: 30611120528)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2009	04/06/2019	Yes	No